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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,317	11/06/2001	Kazuyuki Miyazawa	SHI-017-USA-PCT	4088

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EXAMINER

EBRAHIM, NABILA G

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,317

Applicant(s)

MIYAZAWA ET AL.

Examiner

Nabila G. Ebrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/13/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Receipt of the request for Continued Examination (RCE) under 37 C.F.R. 1.1 14, and Extension of Time of application 09/936,317 filed on 5/13/2005, and amended claims sent 3/31/2005 have been acknowledged.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyazawa et al. US 6,391,288 "Miyazawa" in view of Unger US 5,976,500 "Unger".

Miyazawa teaches a microcapsule having average particle size of 0.01 to 3 μm ; its capsulating agent is a hydrophilic polymer gelling agent. The main component of the

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capsulating agent is preferably a hydrophilic polymer gelling agent, which hardens by heating and cooling, and in particular, agar or carrageenan, and its particle size can easily be controlled (abstract). Miyazawa uses also a water-soluble solvent (col. 3, line 22) and disclosed that natural polymers such as xanthan gum and polycyclic acid and others can be used within a range, which does not deteriorate the effect of the present invention, Miyazawa explains that the microcapsule tends to soften when Keltrol (xanthan gum) is used together with agar (col. 5, lines 19-28). The same compounds are recited in claim 4 as the viscosity increasing compound incapable of forming a gel, though the prior art does not refer to the same properties of these compounds, it is expected that these properties are inherent.

A skilled man in the art would have been motivated to control the softness of a gel using this disclosure of Miyazawa.

Miyazawa disclosed in his invention that hydrophilic polymer gelling agent included in his invention are usually used in cosmetics, medicines and the like (col. 4, lines 57-58). In addition he used his microcapsule to deliver drugs and cosmetics, he teaches that an oil-soluble drug with a low stability is contained in the encapsulated oil droplets, and the stability of the drug can be improved. Examples thereof include easy-to-oxidize drugs such as retinol and vitamin E; and easy-to-crystallize compounds like vitamin C palmitate (a whitening agent) (col. 8, lines 31-36).

Though the instant application recites whitening ingredients like L-ascorbic acid or its derivative, the applicator did not show any unexpected results in using this specific whitening agent, or in using the specific percentages recited in claims 10 and 12.

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Miyazawa also teaches the steps of his invention, which is very similar to the process of the instant application, the steps are:

- Heating and dissolving a hydrophilic polymer gelling agent hardening by heating and cooling into water beforehand so as to prepare an aqueous gelling agent solution.
- Adding it to the oil-in-water soluble solvent type emulsion at a hardening temperature of the gelling agent or higher so as to prepare an O/W emulsion.
- Cooling the system to the hardening temperature or lower so as to harden the water phase, thus making a microcapsule. (col. 6, lines 39-51)
- The last step, recited in the claims of the instant application is the pulverization will be further discussed as the examiner starts discussing Unger disclosure, however, in example I-1 Miyazawa used stirring O/W to the emulsion to get the average size of the particles 0.5 which reads on the definition of the pulverization process in (page 7, the last paragraph) that it is a process of crushing by means of many processes, -one of them is mechanical stirrer- to obtain the microgel.

Miyazawa pulverized the emulsion but he is deficient in pulverizing the gel.

Unger teaches an invention directed to contrast media comprising gel particles, preferably of less than about 90 μm in mean diameter, said gel particles comprising at least one polymer (col. 2, lines 1-9). The gelling polymers that Unger uses include carrageenan, alginic acid, xanthan gum, polycyclic acid, and polyacrylamides (col. 3, lines 10-45). In accordance with Unger invention, the resultant gel may then be treated to form smaller gel particles. Such treatment

may include any one of a variety of techniques, as will be readily apparent to those skilled in the art, such as blenderizing, ball mixing, colloid mixing, etc, as well as any and all combinations thereof. Blenderizing, for example, may be accomplished by using any of a number of commercial blenders, and may be followed, if desired, by extrusion with a commercial extruder device having a filter of a defined size. These and other processes are well known to those skilled in the art. Unger defines in his invention the term particularizing, and variations, to refer to the formation of small particles, preferably of relatively uniform size, by any of the aforementioned or other processes (col. 5, lines 63-67 and col. 6, lines 1-10). The process, which Unger disclosed in his invention, reads on the pulverization that is recited in the claims of the instant application.

Unger adds that the particles sizes can be controlled through the process and that terms nanogels and microgels as used in his invention denote particles ranging from about 1nm to less than 1 μ m and from 1 μ m to about 1000 μ m (microgel), which shows that the particle sizes he could obtain were of a very wide range.

Additionally the instant application does not show any unexpected results of the recited viscosity, the specification explains that the viscosity will not be lowered in case of using a pharmaceutical, but it does not show the criticality of the viscosity values recited in the claims, and using the same compounds in the prior art of Miyazawa, it is expected that the same viscosity will be obtained.

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Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to expand the teachings of Miyazawa and dissolve a hydrophilic gelling polymer in an aqueous solvent, obtain a gel and follow Unger's teaching to crush it into smaller particles as needed for different usages, motivated by the disclosure of Miyazawa that the invention can be used for cosmetics or to deliver pharmaceutical agents and to apply the disclosure of Unger that particles can be crushed into smaller particles through further processes of particularizing with an expectation of a composition that is heat stable and stable in long term storage, both properties that are obvious advantage in commercial use.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nabila Ebrahim, M.D.

9/14/05

Nabila Ebrahim

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